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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,855	10/27/2003	Tuula Ryde	029318-0988	9261

31049 7590 01/12/2007  
ELAN DRUG DELIVERY, INC.  
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WASHINGTON, DC 20007-5109

EXAMINER
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GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/692,855

**Applicant(s)**

RYDE ET AL.

**Examiner**

Konata M. George

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 136 and 140-193 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 136 and 140-193 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/11/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 136 and 140-193 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on July 11, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Action Summary***

2. The objection of claims 140, 141, 143, 148 and 150 as containing a trademark/trade name is hereby withdrawn as applicant has defined what the trademark/trade name is.
3. The rejection of claims 136 and 140-189 under 35 U.S.C. 112, first paragraph, scope of enablement is hereby withdrawn.
4. The rejection of claims 136, 137, 163, 167-171, 173, 184 and 185 under 35 U.S.C. 102(b) as being anticipated by Pace et al. is hereby withdrawn.
5. The rejection of claims 149-152 under 35 U.S.C. 103(a) over Pace et al. is hereby withdrawn.

### ***Claim Objections***

6. Claim 192 contain the trademark/trade name POLYQUAT™, MIRAPOL™ and ALKAQUAT™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a surface stabilizer and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 136 and 140-193 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the Art that the inventor(s), at the time of the application was filed, had Possession of the claimed invention.

The claims encompass the genus of all stable fenofibrate compositions which exhibit the functional definition of being bioequivalent when fed to a human subject in either the fed or fasting state as evidenced by (a) a 90% confidence interval for UAC which is between 0.80 and 1.25 and (b) a 90% confidence interval for  $C_{max}$  which is between 0.80 and 1.25. In support of this composition genus, the specification provides **a written description of only a single stable fenofibrate composition** which meets the functional limitations and is termed "TRICOR®".

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species of stable fenofibrate compositions meeting the FDA guidelines for bioequivalence between fed and fasting states, by actual reduction to practice or by disclosure of relevant identifying characteristics.

The art at the time of filing does not provide sufficient information on the subject of stable fenofibrate compositions to overcome the deficiencies of the

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instant specification. There is no description in the art describing a representative number of stable fenofibrate compositions meeting the specific confidence intervals for AUC and  $C_{\max}$ . There is also nothing in the art to correlate the structure-function relationship of the components of the single embodiment termed TRICOR®. Thus, the skilled artisan cannot rely on the art to envision a sufficient number of embodiments of the instant invention to establish that the applicant was in possession of the claimed genus.

Therefore, the applicant has not satisfied the written description requirement to show the skilled artisan that applicant was in possession of the claimed genus of all stable fenofibrate compositions having the bioequivalence characteristics defined by the AUC and  $C_{\max}$  of claim 136.

Claims limited to the specific stable fenofibrate composition defined by TRICOR® would be have appropriate written descriptive support.

### ***Conclusion***

8. Claims 136 and 140-193 are rejected.

***Telephone Inquiries***

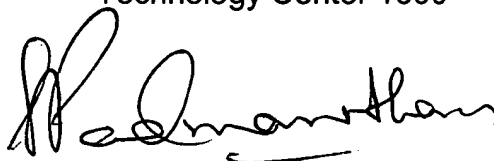
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER

1/8/07